IN THE CLAIMS:

Claims 1-5 and 14 have been amended.

Amendments to the Claims

The listing of claims will replace all prior versions, and listings of claims in the application.

1. (Currently amended) A method for ~~characterising~~ characterizing a cell proliferative disorder of the breast tissues of a human subject comprising;

~~a) obtaining a biological sample comprising genomic DNA from the subject having a cell proliferative disorder of the breast tissue;~~

~~b)~~ determining, by analyzing [~~the~~] genomic DNA from a biological fluid containing DNA from breast cells or tissue; breast tissue; or breast cell sample from the subject having or at risk of having a cell proliferative disorder of the breast, the methylation status of one or more target CpG dinucleotide sequences within the PITX2 gene and/or its regulatory region by contacting [~~said~~] one or more target nucleic acid sequences within the PITX2 gene with one or more agents that convert cytosine bases that are unmethylated at the 5'-position thereof to a base that is detectably dissimilar to cytosine in terms of hybridization properties; and

~~c)~~ determining, based on the methylation status [~~, at least one of:~~] characteristics of the cell proliferative disorder of the subject breast tissue, thereby providing one or more of [;] a prognosis of said subject disease free survival or metastases of said subject; and/or probability of response of said subject to one or more treatment regimens ~~that target the estrogen receptor pathway and/or are involved in estrogen metabolism, production and/or secretion~~, wherein [~~a method for characterising a cell proliferative disorder of the breast tissues of the subject is afforded~~] an increased methylation status in the sample as compared with methylation status in a control sample from a subject not having or at risk of having a cell proliferative disorder of the breast tissue, provides characterization of the cell proliferative disorder.

2. (Currently amended) The method of claim 1, wherein [~~determining in step b) comprises~~] determining the methylation status of one or more target CpG [~~positions~~] sequences within PITX2 is within SEQ ID NO:23 or a portion thereof.

3. (Currently amended) The method of claim 1, further comprising [~~d)~~] determining a suitable treatment regimen for the subject based on the characterization of the disorder.

4. (Currently amended) The method of claim 1, wherein determining ~~in c)~~ comprises predicting the response of the subject with said disorder to a one or more treatments that target the estrogen receptor pathway or are involved in estrogen metabolism, production or secretion.

5. (Currently amended) The method of claim 1, wherein determining ~~in c)~~ comprises characterising a cell proliferative disorder of the breast tissues and/or a metastases thereof; and/or predicting the disease free survival.

6. (Previously presented) The method of claim 1, wherein said one or more treatment regimen comprises one or more therapies selected from the group consisting of chemotherapy, radiotherapy, surgery, biological therapy, immunotherapy, antibodies, molecularly targeted drugs, estrogen receptor modulators, estrogen receptor down-regulators, aromatase inhibitors, ovarian ablation, LHRH analogues and other centrally acting drugs influencing estrogen production.

7. (Previously Presented) The method of claim 1, wherein said one or more treatment comprises an adjuvant treatment.

8. (Previously Presented) The method of claim 2, wherein said one or more treatment comprises an adjuvant treatment.

9. (Withdrawn) The method of claim 1, wherein said disorder is a metastatic disease and said genes are selected from the group consisting of APC, CSPG2, ERBB2, STKll, S100A2, TFF1, TGFBR2, TP53, TMEFF2, SYK, HSPB1, RASSF1, PSAT1, CGA, ESR2, ONECUT2, WBP11, CYP2D6, CDK6, ELK1, CGB and DAG1.

10. (Withdrawn) The method of claim 1, wherein said disorder is a metastatic disease and said target nucleic acid(s) are selected from the group consisting of SEQ ID NOS:2, 4, 5, 7, 11, 12, 13, 14, 17, 19, 20, 21, 25, 26, 29, 35, 37, 45, 46, 53, 55 and SEQ ID NO:59.

11. (Previously presented) The method of claim 1, wherein the genomic DNA is obtained from cells or cellular components from a source selected from the group consisting of cell lines, histological slides, paraffin embedded tissues, biopsies, tissue embedded in paraffin or sections thereof, breast tissues, blood, plasma, serum, lymphatic fluid, lymphatic tissue, duct cells, ductal lavage fluid, nipple aspiration fluid, cerebrospinal fluid, bone marrow and combinations thereof.

12. (Previously presented) The method of claim 1, wherein said cell proliferative disorder of the breast tissue is selected from the group consisting of ductal carcinoma *in situ,* invasive ductal carcinoma, invasive lobular carcinoma, lobular carcinoma *in situ,* comedocarcinoma, inflammatory carcinoma, mucinous carcinoma, scirrhous carcinoma, colloid carcinoma, tubular carcinoma, medullary carcinoma, metaplastic carcinoma, and papillary carcinoma and papillary carcinoma *in situ,* undifferentiated or anaplastic carcinoma and Paget' s disease of the breast.

13. (Previously presented) The method of claim 1, wherein said subjects are estrogen and/or progesterone receptor positive.

14. (Currently amended) The method of claim 1, wherein determining ~~in step b)~~ methylation status comprises:

converting cytosine bases in the genomic DNA sample which are unmethylated at the 5-position, to uracil or another base which is dissimilar to cytosine in terms of base pairing ~~behaviour~~ behavior;

amplifying at least one fragment of the pretreated genomic DNA, wherein said fragments comprise at least 8 base pairs of one or more sequences selected from the group consisting of SEQ ID NOS:250, 251, 372 and SEQ ID NO:373 and sequences complementary thereto, and

determining the methylation status of the one or more target genomic CpG dinucleotides by analysis of the amplificate nucleic acids.

15. (Previously Presented) The method of claim 14, wherein amplifying at least one fragment comprises use of at least one of methylation sensitive PCR (MSP) and heavy methyl (HeavyMethyl) PCR.

16. (Previously Presented) The method of claim 14, wherein determining the methylation status comprises use of one or more methods selected from the group consisting oligonucleotide hybridisation analysis, methylation-sensitive single nucleotide primer sxtension (Ms-SNuPE), sequencing, real-time detection probes and oligonucleotide array analysis.

17. (Withdrawn) A nucleic acid molecule consisting essentially of a sequence at least 18 bases in length according to one of the sequences selected from the group consisting of SEQ ID NOS:206-449.

18. (Withdrawn) An oligomer, in particular an oligonucleotide or peptide nucleic acid (PNA)-oligomer, said oligomer consisting essentially of at least one base sequence having a length of at least 10 nucleotides which hybridises to or is identical to one of the nucleic acid sequences according to SEQ ID NOS:206-449.

19. (Withdrawn) A set of at least two oligonucleotides as recited in claim 18.

20. (Withdrawn) A kit comprising a bisulfite,, disulfite, or hydrogen sulfite) reagent as well as oligonucleotides and/or PNA-oligomers according to one of the Claims 18 or 19.

21. (Withdrawn) The kit of claim 20, further comprising standard reagents for performing a methylation assay from the group consisting of MS-SNuPE, MSP, Methyl light, Heavy Methyl, nucleic acid sequencing and combinations thereof.

22. (Canceled)